

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and)	
NOVO NORDISK A/S,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 21-1783 (CFC)
)	ANDA CASE
HIKMA PHARMACEUTICALS USA)	
INC.,)	
)	
Defendant.)	

JOINT CLAIM CONSTRUCTION CHART

Pursuant to paragraph 19 of the Scheduling Order (D.I. 17), Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Novo Nordisk”) and Hikma Pharmaceuticals USA, Inc. (“Hikma”) respectfully submit the attached Joint Claim Construction Chart, addressing the claim construction positions of the parties regarding U.S. Patent Nos. 8,114,833 (the “’833 patent”) and 9,265,893 (the “’893 patent”) (collectively, the “Asserted Patents”).

The parties jointly propose construction of certain terms from the ’833 patent and ’893 patent consistent with the constructions by the Court in prior Hatch-Waxman litigations involving these two patents. *See Novo Nordisk Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, No. 17-cv-227, D.I. 61, 68 (D. Del.); *Novo Nordisk Inc. et al. v. Mylan Institutional LLC*, No. 19-cv-1551, D.I. 106 (D. Del.); *Novo Nordisk*

Inc. et al. v. Sandoz Inc., No. 20-cv-747, D.I. 103 (D. Del.) (collectively, the “Prior Litigations”).

Hikma has proposed five additional terms from the ’893 patent for construction, and Novo Nordisk has posited that no construction of these terms is necessary (the “Disputed Claim Terms”). As detailed in the Stipulation and Proposed Order Regarding Claim Construction filed herewith, the Court was previously presented with the same claim terms in *Novo Nordisk Inc. et al. v. Sandoz, Inc.*, C.A. No. 20-cv-747-CFC (D. Del.) (the “Sandoz Litigation”). At the Claim Construction Hearing in the Sandoz Litigation, the Court deferred any decision on the Disputed Claim Terms until trial, given the case would not be tried to a jury and expert testimony would benefit the Court. *See Novo Nordisk Inc. et al. v. Sandoz, Inc.*, C.A. No. 20-cv-747-CFC (D.I. No. 103; July 1, 2021 *Markman* Hearing Transcript at pp. 74-84). Subject to the Court’s approval, the parties similarly seek to defer any decision on construction of the Disputed Claim Terms until trial in this case. To the extent that disputes remain at the close of expert discovery, in connection with preparation of the pretrial order, the parties will brief their respective positions according to the claim construction briefing instructions set out in the Scheduling Order (D.I. 17, Para. 20).

The parties agree that any terms in the asserted claims of the Asserted Patents that do not appear in the Joint Claim Construction Chart below, should be given their

respective plain and ordinary meanings as understood by a person of ordinary skill in the art in light of the specification of the patent in which they appear, and thus do not require construction by the Court. The parties reserve the right to rely on additional intrinsic evidence to the extent it is necessary to provide additional context or to rebut arguments made by other parties. The parties further reserve the right to rely on any intrinsic evidence identified by any other party. The parties reserve the right to update and/or supplement their proposed claim constructions as discovery proceeds in this case.

The parties intend to rely on the Asserted Patents, the specifications of the Asserted Patents, the claims of the Asserted Patents, the file histories of the Asserted Patents, and patents and applications to which the Asserted Patents claim priority or which claim priority to the Asserted Patents. Any citation to intrinsic evidence provided by the parties in support of their proposed claim constructions is intended as exemplary. Any additional evidence or reference within or encompassed by a particular citation is deemed incorporated by reference (e.g., cited passages are intended to include all figures and tables referenced therein). The parties also reserve the right to rely on extrinsic evidence and/or expert declaration or testimony in support of their proposed constructions or to rebut the other party's arguments and/or any expert declaration or testimony submitted by the other party.

Copies of the '833 patent and '893 patent are attached hereto as Exhibits A and B, respectively.

MORRIS, NICHOLS, ARSHT &
TUNNELL LLP

/s/ Travis J. Murray

Jack B. Blumenfeld (#1014)
Brian P. Egan (#6227)
Travis J. Murray (#6882)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
began@morrisnichols.com
tmurray@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

Jeffrey J. Oelke
Ryan P. Johnson
Robert E. Counihan
Laura T. Moran
Erica R. Sutter
Olivia L. Wheeling
FENWICK & WEST LLP
902 Broadway, Suite 14
New York, NY 10010-6035
(212) 430-2600

November 9, 2022

DEVLIN LAW FIRM LLC

/s/ James M. Lennon

James M. Lennon (#4570)
1526 Gilpin Avenue
Wilmington, DE 19806
(302) 449-9010
jlennon@devlinlawfirm.com

Attorneys for Defendant

OF COUNSEL:

Charles B. Klein, Esquire
Sharon Lin, Esquire
WINSTON & STRAWN LLP
1901 K Street N.W.
Washington, DC 20036
(202) 282-5000

Novo Nordisk Inc. et al. v. Hikma Pharmaceuticals USA Inc.
Civil Action No. 21-1783 (CFC)
Joint Claim Construction Chart

CLAIM TERMS AGREED UPON FROM THE PRIOR LITIGATIONS IN U.S. PATENT NO. 8,114,833		
Term	Affected Claims	Parties' Proposed Construction
“replacing the isotonicity agent previously utilized in said formulation with propylene glycol”	23, 26, and 29	“Having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first formulation is substituted or replaced with propylene glycol”
“the isotonicity agent to be replaced by propylene glycol”	25, 28, and 31	“Having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first formulation is substituted or replaced with propylene glycol”
“about [when used in connection with pH]”	1, 3, 4, 7, 8, 9, 16, 18, and 19	When used in connection with pH, “[plus] or [minus] 0.1 pH units from [the stated number]”
“disodium phosphate dihydrate”	1, 3, 4, 7-14, 16, 18, 19, 23, 25, 26, 28, 29, and 31	“dihydrate form of disodium hydrogen phosphate having molecular formula $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$,” which is the plain and ordinary meaning in view of the intrinsic evidence

CLAIM TERMS AGREED UPON FROM THE PRIOR LITIGATIONS IN U.S. PATENT NO. 8,114,833		
Term	Affected Claims	Parties' Proposed Construction
"A method for reducing deposits on production equipment during production of a GLP-1 agonist formulation"	23 and 25	The phrase is an express limitation of claim 23 and it carries its plain and ordinary meaning.
"A method for reducing deposits in the final product during production of a GLP-1 agonist formulation"	26 and 28	The phrase is an express limitation of claim 26 and it carries its plain and ordinary meaning.
"A method for reducing the clogging of injection devices by a GLP-1 agonist formulation"	29 and 31	The phrase is an express limitation of claim 29 and it carries its plain and ordinary meaning.

CLAIM TERMS AGREED UPON FROM THE PRIOR LITIGATIONS IN U.S. PATENT NO. 9,265,893		
Term	Affected Claims	Parties' Proposed Construction
"driving part"	1-6	"a part that transfers force from the push button"
"pivot bearing"	1-6	"a bearing that supports an end of a rotating shaft subject to an axial load"
"radial bearing"	2-4	"a bearing that supports a load on a shaft that is perpendicular to the axis of rotation"
"protrusion"	1-6	Plain and ordinary meaning, which is "something that protrudes"

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
"bore"	1-6	No construction necessary. To the extent the Court	'893 Patent Specification: - Abstract - Col.2, ll.27-31 - Col.2, l.55 – Col.3,	Plain and ordinary meaning, i.e., a hole having a circular	'893 patent at Abstract, 1:15-20, 1:24-39, 1:43-2:31, 2:35-3:3, 3:5-18, 3:20-4:37, Figs. 1-2, Claims 1-6

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
		finds that construction is necessary: Plain and ordinary meaning, which is "a hole in a three-dimensional part"	<p>1.19</p> <ul style="list-style-type: none"> - Col.3, ll.61-64 - Col.4, ll.12-19 - Col.4, ll.33-38 - Figures 1 & 2 <p>File History of the '893 Patent: NNVICT-HIKMA_00003888-5159, including for example:</p> <p>PCT Patent Application WO 99/38554 (NNVICT-HIKMA_00003911-3937);</p> <p>PCT Patent Application WO 93/07922 (NNVICT-HIKMA_00003941-3954;</p>	cross-section	'893 patent file history

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
			<p>PCT Patent Application WO 2008/095762 (NNVICT-HIKMA_00003957-3967);</p> <p>EP Application 07101729 (NNVICT-HIKMA_00003972-3982);</p> <p>July 25, 2013 Appeal Brief (NNVICT-HIKMA_00004237-4258)</p>		
"bottom surface [of the bore]"	1-6	No construction necessary. To the extent the Court finds that	<p>'893 Patent Specification:</p> <ul style="list-style-type: none"> - Abstract - Col.1, ll.43-56 - Col.2, ll.27-31 - Col.2, l.55 – Col.3, 	Plain and ordinary meaning, i.e., most proximal surface [of	'893 patent at Abstract, 1:15-20, 1:24-39, 1:43-2:31, 2:35-3:3, 3:5-18, 3:20-4:37, Figs. 1-2, Claims 1-6

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
		construction is necessary: Plain and ordinary meaning, which is "the exposed surface of the bore"	<p>1.19</p> <ul style="list-style-type: none"> - Col.3, ll.21-34 - Col.3, ll.43-60 - Col.3, ll.61-64 - Col.4, ll.11-19 - Col.4, ll.34-38 - Figures 1 & 2 <p>File History of the '893 Patent: NNVICT-HIKMA_00003888-5159, including for example: PCT Patent Application WO 99/38554 (NNVICT-HIKMA_00003911-3937); PCT Patent Application WO 93/07922 (NNVICT-HIKMA_00003941-3954);</p>	the bore], where "proximal" means situated near the push surface of the push button, and away from the injection needle	'893 patent file history

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
			<p>PCT Patent Application WO 2008/095762 (NNVICT-HIKMA_00003957-3967);</p> <p>EP Application 07101729 (NNVICT-HIKMA_00003972-3982);</p> <p>July 25, 2013 Appeal Brief (NNVICT-HIKMA_00004237-4258)</p>		
“top surface [of the protrusion]”	1-6	No construction necessary. To the extent the Court finds that construction is necessary: Plain and	<p>'893 Patent Specification:</p> <ul style="list-style-type: none"> - Abstract - Col.2, l.55 – Col.3, l.19 - Col.3, ll.21-34 - Col.3, l.65 – Col.4, l.2 - Col.4, ll.11-19 - Col.4, ll.34-38 	Plain and ordinary meaning, i.e., most proximal surface [of the protrusion], where	<p>'893 patent at Abstract, 1:15-20, 1:24-39, 1:43-2:31, 2:35-3:3, 3:5-18, 3:20-4:37, Figs. 1-2, Claims 1-6</p> <p>'893 patent file history</p>

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
		ordinary meaning, which is "the exposed surface of the protrusion"	<p>- Figures 1 & 2</p> <p>File History of the '893 Patent: NNVICT-HIKMA _00003888-5159, including for example:</p> <p>PCT Patent Application WO 99/38554 (NNVICT-HIKMA _00003911-3937);</p> <p>PCT Patent Application WO 93/07922 (NNVICT-HIKMA _00003941-3954);</p> <p>PCT Patent Application WO 2008/095762 (NNVICT-HIKMA _00003957-3967);</p> <p>EP Application</p>	"proximal" means situated near the push surface of the push button and away from the injection needle	

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
			07101729 (NNVICT-HIKMA_00003972-3982); July 25, 2013 Appeal Brief (NNVICT-HIKMA_00004237-4258)		
"upper radial bearing is provided at the top part of the protrusion"	3	No construction necessary. To the extent the Court finds that construction is necessary: Plain and ordinary meaning, which is "radial bearing is provided at a portion of the	'893 Patent Specification: - Abstract - Col.1, 1.53 – Col.2, 1.15 - Col.2, 1.55 – Col.3, 1.19 - Col.3, 11.21-34 - Col.4, 11.11-33 - Col.4, 11.34-38 - Figures 1 & 2 File History of the '893 Patent: NNVICT-HIKMA_00003888-5159,	Plain and ordinary meaning, i.e., radial bearing is provided at the most proximal segment on the outside of the protrusion, where "proximal" means situated near the push	'893 patent at Abstract, 1:15-20, 1:24-39, 1:43-2:31, 2:35-3:3, 3:5-18, 3:20-4:37, Figs. 1-2, Claims 1-6 '893 patent file history

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
		protrusion that is nearer the furthest extent of the protrusion than the end opposite the furthest extent of the protrusion"	<p>including for example:</p> <p>PCT Patent Application WO 99/38554 (NNVICT-HIKMA _00003911-3937);</p> <p>PCT Patent Application WO 93/07922 (NNVICT-HIKMA _00003941-3954);</p> <p>PCT Patent Application WO 2008/095762 (NNVICT-HIKMA _00003957-3967);</p> <p>EP Application 07101729 (NNVICT-HIKMA _00003972-3982);</p> <p>July 25, 2013 Appeal Brief</p>	surface of the push button and away from the injection needle	

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
			(NNVICT-HIKMA _00004237-4258)		
"lower radial bearing is provided at the bottom of the protrusion"	3	No construction necessary. To the extent the Court finds that construction is necessary: Plain and ordinary meaning, which is "radial bearing provided at a portion of the protrusion that is nearer the end opposite the furthest extent of the	<p>'893 Patent Specification:</p> <ul style="list-style-type: none"> - Abstract - Col.1, l.53 – Col.2, l.15 - Col.2, l.55 – Col.3, l.19 - Col.3, ll.21-34 - Col.4, ll.11-33 - Col.4, ll.34-38 - Figures 1 & 2 <p>File History of the '893 Patent: NNVICT-HIKMA _00003888-5159, including for example:</p> <p>PCT Patent Application WO 99/38554 (NNVICT-HIKMA _00003911-3937);</p>	Plain and ordinary meaning, i.e., radial bearing is provided at the most distal segment on the outside of the protrusion, where "distal" means situated near the injection needle and away from the push surface of the push button	<p>'893 patent at Abstract, 1:15-20, 1:24-39, 1:43-2:31, 2:35-3:3, 3:5-18, 3:20-4:37, Figs. 1-2, Claims 1-6</p> <p>'893 patent file history</p>

DISPUTED CLAIM TERMS IN U.S. PATENT NO. 8,114,893					
Term for Construction	Affected Claims	Plaintiffs' Proposed Construction	Plaintiffs' Intrinsic Evidence	Defendant's Proposed Construction	Defendant's Intrinsic Evidence
		protrusion than the furthest extent of the protrusion”	<p>PCT Patent Application WO 93/07922 (NNVICT-HIKMA _00003941-3954);</p> <p>PCT Patent Application WO 2008/095762 (NNVICT-HIKMA _00003957-3967);</p> <p>EP Application 07101729 (NNVICT-HIKMA _00003972-3982);</p> <p>July 25, 2013 Appeal Brief (NNVICT-HIKMA _00004237-4258)</p>		